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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,553	12/06/2005	David G. Matsuura	355908-8201	9456

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EXAMINER	
HAND, MELANIE JO	
ART UNIT	**PAPER NUMBER**
3761	
MAIL DATE	**DELIVERY MODE**
09/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,553	MATSUURA ET AL.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *12 and 23-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-22,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of group I, claims 1-11, 13-22, 35 and 36 in the reply filed on July 6, 2007 is acknowledged. Applicant's election with traverse of group I, claims 1-11, 13-22, 35 and 36 in the reply filed on July 6, 2007 is acknowledged. The traversal is on the ground(s) that the Office did not articulate why the cited art either anticipated or rendered obvious the claimed invention. This is not found persuasive because the Office is not required to state why the prior art anticipates or renders obvious the claimed invention, only that the inventions are independent and distinct and that serious burden would be placed upon the examiner to search all of the claims. See MPEP §808.

The requirement is still deemed proper and is therefore made FINAL.

Claims 12 and 23-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Priority

Acknowledgment is made of applicant's claim for priority from copending provisional Application No. 60/421,781, filed on October 29, 2002.

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 371.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 16, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-11, 13-15 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Pall Corporation (hereafter "Pall") (GB 1,297,794).

With respect to claim 1: Pall teaches a syringe assembly, comprising: an elongate container 45 with a plunger 22 slidably and sealingly engaged therein to form a cavity to receive fluid materials, the fluid materials including a nongaseous constituent (e.g. blood) and a gaseous constituent (air), the

container 45 further comprising a first outlet at apertured tip 47 for dispensing fluid materials from the cavity under the action of the plunger 22. Gaseous material collection housing 55 has a fluid materials receiving chamber 54, the housing having a first inlet defined by passageway 17 of leg 11 of housing 55 to couple with the first outlet 47. The housing 55 has a second outlet defined by passageway 19 of leg 15 of housing 55 and a second outlet valve portion 73 for controlling the passage of the gaseous constituent from the chamber through the second outlet

to a region outside the housing while retaining the non-gaseous constituent within the chamber. (Figs. 1,2, Page 2, lines 110-122, Page 4, lines 3-21, 104-108, 120-129)

With respect to **claim 2:** Pall teaches an assembly further comprising a first inlet valve portion 12 for controlling the passage of the fluid materials through the first inlet. (Page 5, lines 8-19, 68-70)

With respect to **claim 3:** The first valve portion 12 includes a valve plate in the form of valve seat 61 that is integral with insert 52 that is permanently fixed in bore 62 defining passageway 17 of housing 55. The plate 61 is therefore sealingly anchored with the housing 55 adjacent a duck bill valve 68. (Fig. 3, Page 5, lines 8-19)

With respect to **claim 4:** The second outlet valve portion 73 includes a hydrophobic media layer in the form of a polyester-modified polyurethane foam layer 13. (Page 5, lines 32-41)

With respect to **claim 5:** The hydrophobic media layer 13 includes a first surface facing the chamber and an opposite second surface, the second outlet valve portion 73 further including an external housing in the form of insert 53 adjacent the second surface. (Fig. 3, Page 4, lines 120-125)

With respect to claim **7:** The second outlet valve portion 73 includes a hydrophobic filter media layer in the form of polyurethane foam 13 mentioned *supra* sealingly anchored with the housing adjacent the second outlet. (Page 5, lines 32-41,53,54)

With respect to **claim 8:** The hydrophobic filter media layer 13 includes a substantially wetting membrane, as the layer is comprised of foam. (Page 5, lines 32-41,53,54)

With respect to **claim 9:** At least a portion of the housing 55, which is comprised of polyvinyl chloride, which is transparent, is arranged to view fluid materials accumulating therein. (Page 4, line 115)

With respect to **claim 10:** The portion of housing 55 is comprised of polyvinyl chloride, which is transparent. (Page 4, line 115)

With respect to **claim 11:** Pall teaches that substantially the entire housing 55 is constructed of polyvinyl chloride, which is transparent. (Page 4, line 115)

With respect to **claim 13:** Pall teaches a method for discharging gaseous materials from a medical materials dispenser, comprising the steps of: filling a medical materials dispenser in the form of syringe 20 with fluid materials; fitting an outlet (apertured tip 47) of the dispenser with an inlet 11 of a collection housing 55, which is arranged to receive fluid materials from the syringe cavity and which has the capability of selectively emitting a gaseous constituent of the material from the housing, and of retaining one or more non-gaseous fluid constituents in the housing via a filter media layer 13; orienting the dispenser 20 to collect the gaseous constituent adjacent the outlet 47; and activating the dispenser 20 by depressing plunger 22 so that at least the gaseous constituent exits the outlet and enters the housing 55 wherein the dispensing step may include the emission of the gaseous constituent from the housing through filter 13 while the non-

gaseous residual materials are substantially retained therein.

With respect to **claim 14:** Pall teaches a method further comprising the steps of removing the collection housing 55 from the dispenser 20 and actuating the dispenser 20 to administer the fluid materials.

With respect to **claim 15:** The dispenser includes a syringe 20.

With respect to claim 36: Pall teaches a dispenser assembly 20, comprising: an elongate container 45 with a plunger 22 slidably and sealingly engaged therein to form a cavity to receive fluid materials, the fluid materials including a nongaseous constituent (blood) and a gaseous constituent (air), the container 45 further comprising a first outlet at apertured tip 47 for dispensing fluid materials from the cavity under the action of the plunger 22; a gaseous material collection housing 55 having a fluid materials receiving chamber 54, the housing having a first inlet 17 to couple with the first outlet 47; and the housing having a second outlet 19 and a valve assembly 73 for controlling the passage of the gaseous constituent from the chamber through the second outlet to a region outside the housing while retaining the non-gaseous constituent within the chamber via filter media layer 13 therein; the valve assembly including a first valve portion including an hydrophobic media layer 13 and a normally closed second valve portion in the form of duckbill valve 68 spaced from the first valve portion 13 to form an intermediate

chamber therebetween bounded by the media layer 13, the inner wall of insert 53 and the outer surface of duckbill valve 68 in Fig. 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pall in view of any of DiMatteo et al (U.S. Patent Application Publication No. 2002/0188348), Swisher et al (U.S. Patent Application Publication No. 2002/0173757) and Phillips (U.S. Patent No. 5,380,277).

With respect to **claim 6:** Pall teaches that valve plate 61 does not explicitly teach that valve plate 61 is spring biased to a closed position to form a unidirectional valve. However spring-biased valves having valve plates therein that are biased to a normally closed position are known in the art (see U.S. Patent Application Publication Nos.

2002/0188348 to to DiMatteo et al, 2002/0173757 to Swisher et al, and U.S. Patent No. 5,380,277 to Phillips), therefore it would be obvious to one of ordinary skill in the art to modify the device of Pall so as to have a valve plate in said first valve portion that is spring biased to a normally closed position with a reasonable expectation of success to prevent undesired flow in any direction that will cause contamination of either the ambient environment or the fluid material received therein.

Claims 16-22 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tremblay et al (U.S. Patent No. 6,136,308) in view of Pall ('794).

With respect to **claim 16:** Tremblay teaches a process for treating a mammalian patient, which comprises: extracting an aliquot of the patient's blood, necessarily with a first medical materials dispenser (Col. 3, lines 7,8); subjecting the aliquot of blood extracorporeally to at least one stressor selected from an oxidative environment, UV radiation and elevated temperature up to about 45° C. (Col. 3, lines 8-11); delivering the so-treated aliquot of blood for injection, which necessarily occurs intravenously from a chamber of a second medical materials dispenser (Col. 3, lines 11,12, Col. 6, lines 5-8). Tremblay teaches administering the so-treated aliquot of blood from the second medical materials dispenser to the patient. (Col. 3, lines 11,12)

Tremblay does not teach fitting an outlet of the second medical materials dispenser with an inlet of a residual material collection housing which is arranged to receive residual fluid materials from the chamber and which has the capability of emitting a gaseous component of the material from the housing, and of retaining substantially all non-gaseous fluid materials in the housing. Pall teaches a medical materials dispenser in the form of syringe 20 having chamber 45 and teaches fitting an outlet (apertured tip 47) of said dispenser with an inlet 17 of a residual material collection housing 55 which is arranged to receive residual fluid materials from

the chamber 45 and which has the capability of emitting a gaseous component of the material from the housing, and of retaining substantially all non-gaseous fluid materials in the housing via filter media layer 13. Pall teaches that the housing 55 (defining T-connector 10) is part of a sterilizing apparatus that ensures that flow from the syringe 20 is one-way only, preventing contamination, therefore it would be obvious to one of ordinary skill in the art to modify the method of Tremblay so as to include the step of fitting an outlet of said medical materials dispenser with the inlet of a residual material collection housing as taught by Pall to ensure one-way flow of the material from the syringe and provide a sterile environment for the transfer of medical material from the dispenser.

Tremblay also does not teach the claimed orienting step. Pall teaches orienting the second medical materials dispenser 20 to collect, at the outlet 47, a gaseous constituent (air) in the fluid material within the chamber 45, dispensing the medical materials dispenser 20 by depressing plunger 22 so that at least the gas constituent exits the outlet and enters the housing 55. The motivation to modify the method of Tremblay in the manner taught by Pall is stated *supra*.

With respect to **claim 17:** The oxidative environment stressor taught by Tremblay to which the blood aliquot is subjected is a mixture of medical grade oxygen and ozone, with an ozone content from about 0.1-100 µg/ml, the ultraviolet radiation stressor is ultraviolet radiation from UV lamps emitting primarily at wavelengths of 280 nm or shorter, and the elevated temperature stressor is a temperature in the range from about 38-43° C. (Col. 4, lines 48-50, lines 54-62, Col. 5, lines 5-12)

With respect to **claim 18:** The blood aliquot is of volume of about 0.1 ml to 400 ml. (Col. 3, lines 65-67)

With respect to **claim 19:** The chosen stressor or combination of stressors is applied to the blood aliquot for a period of time from 0.5-60 minutes. (Col. 5, lines 63-66)

With respect to **claim 20:** The oxidative environment stressor to which the blood aliquot is subjected is a mixture of medical grade oxygen and ozone, with an ozone content from about 0.1-100 µg/ml. (Col. 4, lines 60-62)

With respect to **claim 21:** The ultraviolet radiation stressor is ultraviolet radiation from UV lamps emitting primarily at wavelengths of 280 nm or shorter. (Col. 5, lines 5-12)

With respect to **claim 22:** The elevated temperature stressor is a temperature in the range from about 38-43° C. (Col. 4, lines 48-51)

With respect to claim 35: Tremblay teaches a process for treating a mammalian patient, which comprises: a step for extracting an aliquot of the patient's blood with a first medical materials dispenser (Col. 3, lines 7,8); a step for subjecting the aliquot of blood extracorporeally to at least one stressor selected from an oxidative environment, UV radiation and elevated temperature up to about 45° C. (Col. 3, lines 8-11); delivering the so-treated aliquot of blood for injection, which necessarily occurs intravenously from a chamber of a second medical materials dispenser (Col. 3, lines 11,12, Col. 6, lines 5-8). Tremblay teaches administering the so-treated aliquot of blood from the second medical materials dispenser to the patient. (Col. 3, lines 11,12)

Tremblay does not teach fitting an outlet of the second medical materials dispenser with an inlet of a residual material collection housing which is arranged to receive residual fluid materials from the chamber and which has the capability of emitting a gaseous component of the material from the housing, and of retaining substantially all non-gaseous fluid materials in the housing. Pall teaches a medical materials dispenser in the form of syringe 20 having chamber 45 and teaches fitting an outlet (apertured tip 47) of said dispenser with an inlet 17 of a residual material collection housing 55 which is arranged to receive residual fluid materials from the chamber 45 and which has the capability of emitting a gaseous component of the material from the housing, and of retaining substantially all non-gaseous fluid materials in the housing via filter media layer 13. Pall teaches that the housing 55 (defining T-connector 10) is part of a sterilizing apparatus that ensures that flow from the syringe 20 is one-way only, preventing contamination, therefore it would be obvious to one of ordinary skill in the art to modify the method of Tremblay so as to include the step of fitting an outlet of said medical materials dispenser with the inlet of a residual material collection housing as taught by Pall to ensure one-way flow of the material from the syringe and provide a sterile environment for the transfer of medical material from the dispenser.

Tremblay also does not teach the claimed orienting step. Pall teaches orienting the second medical materials dispenser 20 to collect, at the outlet 47, a gaseous constituent (air) in the fluid material within the chamber 45, dispensing the medical materials dispenser 20 by depressing plunger 22 so that at least the gas constituent exits the outlet and enters the housing 55. The motivation to modify the method of Tremblay in the manner taught by Pall is stated *supra*.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

September 14, 2007

TATYANA ZALUKAEVA
PRIMARY EXAMINER